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MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck E.F.
Chief, Acute Care Policy and Planning

DATE: July 21, 2016

RE: Staff Recommendation for Proposed Permanent Regulations
State Health Plan for Facilities and Services: Freestanding Medical Facilities
COMAR 10.24.15; Analysis of Comments Received

Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as proposed permanent regulations COMAR 10.24.15: State Health Plan Chapter for Freestanding Medical Facilities ("Chapter"). A initial draft Chapter was posted for informal public comment on December 17, 2015 and six organizations commented on this draft Chapter. The Commission advised that postponing this step until after the legislative session would be appropriate, given that staff anticipated that changes in the statute (SB 707 in the 2016 General Assembly Session), would permit an exemption from Certificate of Need (CON) to be granted to a general hospital seeking to convert to a freestanding medical facility (FMF. As expected, those changes in the law occurred and became effective on July 1, 2016. Accordingly, staff developed revised draft Chapter to reflect those changes and convened the FMF Work Group to discuss the draft changes. A further revised draft Chapter was posted for informal public comment on June 23, 2016. Four organizations and one individual commented on the draft Chapter. A copy of the informal comments received is available on the MHCC web site.[1]

The posting of draft regulations for informal comment is not required by law. However, the Commission often has sought informal comments on draft regulations, concluding that receipt of informal comments on draft regulations facilitates a more efficient process and results in better regulations. This process also reduces the likelihood that comments received during the required formal 30-day comment period for proposed regulations will cause the adoption process to begin anew because the Commission desires substantive additional changes.

[1] http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

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A summary of the comments received in both informal comment periods, and Staff's response to these comments is presented below.

Staff Analysis and Recommendations Regarding Informal Comments Received on Draft Freestanding Medical Facilities Chapters

MHCC received informal public comments on the first draft of COMAR 10.24.19 posted in December 2015 from Adventist HealthCare, Anne Arundel Medical Center (AAMC), LifeBridge Health, the Maryland Institute for Emergency Medical Services Systems (MIEMSS), the South of Sligo Citizens' Association (SOSCA), and the University of Maryland Medical System (UMMS). Staff also received informal comments on the revised draft of COMAR 10.24.19 posted in June 2016 from Dimensions Healthcare System, the Maryland Hospital Association, the City of Takoma Park, the University of Maryland Medical System, and David B. Paris, Esquire. A summary of the comments submitted is presented followed by Staff's response to the comments.

.02 Introduction

D. Applicability

AAMC requested clarification on whether a CON is required to close an FMF.

Staff Analysis and Recommendation

Staff will be recommending changes to the procedural regulations, COMAR 10.24.01, rather than to the Freestanding Medical Facilities Chapter to address the concern raised by AAMC. Staff concludes that a public informational hearing may be required prior to closure of an FMF, but a CON is not required to close an FMF based on the most recent applicable statutory changes.

.03 Issues and Policies

Introduction

In response to both the first draft Chapter and the draft Chapter posted in June 2016, UMMS requested that this section include a discussion of the medical services authorized to be provided by an FMF, noting that these services are not limited to emergency services and may include other outpatient services. UMMS also requested changes in other sections of the draft regulations in conjunction with its proposed changes to this section. Similarly, Dimensions Healthcare System requested that a broader range of services be permitted in FMFs beyond emergency services and expressed support for all of the comments submitted by UMMS in response to the draft Chapter posted in June 2016. The Maryland Hospital Association (MHA) requested clarification on whether medical services other than those identified in existing statutes and regulations are permissible in an FMF. MHA specifically asked if ambulatory surgical services are permitted.

Adventist HealthCare commented on the draft Chapter posted in December 2015 that it agreed with the statement that an FMF must "be an administrative part of an acute care general hospital and be physically separated from the hospital or hospital grounds." In addition, Adventist HealthCare also stated that consideration for future FMFs should be limited to improving access to emergency medical care or to reducing overcrowding of the parent hospital's emergency department (ED).

AAMC commented on the draft Chapter posted in December 2015 that the last sentence of this section should be clarified to state that the three existing FMFs were not required to obtain a CON to be established. However, these facilities would require a CON to expand or relocate and for expenditures in excess of the capital threshold for CON projects. AAMC also commented that the impact of an FMF on the closest hospital should be considered.

Staff Analysis and Recommendations

In response to comments from Dimensions Healthcare System, MHA, and UMMS, Staff modified the last sentence on page 14 of the draft Chapter to acknowledge that FMFs may potentially provide other outpatient services. UMMS specifically suggested a change to this sentence. Staff notes, with respect to this change, that FMFs were established in law and are defined in licensure regulation, as facilities for unscheduled medical care that are staffed and equipped for emergency and urgent care, including advanced life support. To the extent that FMFs may be designed to include, in their physical facilities, other outpatient services, these services may be subject to licensure or certification requirements administered by other State agencies or the federal government. Furthermore, the recognition in these regulations that such other outpatient services may potentially be developed as part of an FMF development does not imply any obligation on the part of HSCRC to recognize that these other outpatient services are rate regulated. The new Maryland law leaves to HSCRC the decision on rate regulation of outpatient services on a campus that includes an FMF. Staff also added language to COMAR 10.24.19.04C that permits a general hospital seeking an exemption from CON to convert the hospital to an FMF to seek an exemption from CON to establish an ambulatory surgical facility on the same campus as the FMF.

Staff recommends no changes in response to Adventist HealthCare's comment that future FMF development should be limited to the purposes of improving access to emergency care and reducing overcrowding in the parent hospital's emergency department. Amendments to the law enacted in 2016 permit conversion of a general hospital to an FMF. Therefore, limiting the development of an FMF, as proposed by Adventist HealthCare, would be inconsistent with the new Maryland law. Staff notes that Adventist HealthCare's comments preceded the change in Maryland law. Staff also notes that the regulations recommended for adoption provide that improving access and reducing ED overcrowding are the key bases for justification of a satellite FMF considered in a CON review.

Staff recommends no change in response to AAMC's comment regarding the applicability of the draft Chapter to the existing FMFs that began as pilot projects because no change is necessary. The sentence referenced cites the law as a source, and the law states that a CON is not required for a pilot freestanding medical facility. The existing facilities are no longer

pilot FMFs, so there would be no legal basis for allowing the relocation or expansion of these facilities without a CON. Staff also recommends no change in response to AAMC's comments regarding the evaluation of the impact of an FMF because the impact standards in .04B(7) specify that an applicant is required to project the impact of the proposed FMF on hospitals and FMFs with a service area that substantially overlaps with either the parent hospital's ED or the projected service area of the proposed FMF.

Access to Care

AAMC asked about the causes of overcrowding and long wait times in emergency departments as reported by The American College of Emergency Physicians (ACEP 2014 report), which was used by MHCC staff as a reference in the draft Chapter. AAMC also asked if the conversion of general hospitals to FMFs will ease these conditions.

Staff Analysis and Recommendations

Staff recommends no changes in response to AAMC's questions. Staff is unable to add the additional details requested by AAMC. Staff recommends that AAMC seek additional information from The American College of Emergency Physicians and through additional research.

Rate Regulation

AAMC also sought clarification on how adjustments to the global budgets of other health care facilities will be made by the Health Services Cost Review Commission (HSCRC) when an FMF is replacing an acute care hospital.

Adventist HealthCare commented that the only way for an FMF to be viable is with an appropriate reimbursement structure and urged close collaboration between MHCC and HSCRC, without proposing specific changes to the regulations.

Staff Analysis and Recommendations

HSCRC has sole authority over the global budgets of Maryland hospitals and FMFs. Staff concludes that it is inappropriate for this Chapter to address how HSCRC will handle hospital conversions to FMFs in its global budgeting process.

Staff recommends no changes to address the comments of AAMC or Adventist HealthCare. Staff concludes that the Chapter adequately outlines the bases upon which MHCC will consider a finding of viability. Staff will consult with HSCRC on all CON applications for FMFs and all CON exemption requests for FMFs, because FMFs are rate-regulated hospital facilities.

Policy Objectives

AAMC commented that Policy 5 should provide more detail on how the primary care needs of the population should be assessed. AAMC also asked for clarification on whether the locally developed community health needs assessment should be the source of information on the health needs of the community. In addition, AAMC asked for specific strategies that should be used to educate people to avoid unnecessary use of emergency services.

Staff Analysis and Recommendations

The policy objectives serve as the basis for specific standards included in the draft Chapter. The policy objectives are not intended to provide guidance on implementation of policies, as requested by AAMC. Consequently, Staff recommends no changes in response to AAMC's comments.

.04 Standards

A. General Standards

AAMC commented on the draft posted in December 2015 that these standards should state that an applicant must be the parent hospital for an FMF rather than a multi-hospital health system. David B. Paris, Esquire, commented on the draft posted in June 2016 that MHCC should encourage FMF applications from qualified independent medical entities. He mentioned Kaiser Permanente and Geisinger Health system as examples of potential FMF operators.

Staff Analysis and Recommendations

Prior to posting a second draft Chapter for informal comment in June 2016, Staff modified the language in draft COMAR 10.24.19.04A(1) to state that the parent hospital is the CON applicant, and in draft proposed COMAR 10.24.19.04C(3)(b) to state that the parent hospital and converting hospital must be joint applicants for an exemption from CON review. Staff recommends no additional changes to address Mr. Paris's comment that independent medical entities be allowed to operate FMFs because Maryland statute requires that an FMF be operated by a hospital. In addition, CMS regulations for provider based status may limit who may operate an FMF.

B. Project Review Standards

(1) Need

LifeBridge Health proposed that the term "service area" in Paragraph (a) be replaced by the term "primary service area" because of the amount of overlap when a broader definition is used. LifeBridge Health stated that the Commission would have to decide who should fill the need for an FMF if there is overlap among hospital service areas. LifeBridge Health also commented that because physician contracts may have a large impact on patient throughput and quality, physician contracting should be addressed in the draft Chapter.

SOSCA commented that while applicants who propose an FMF based on overcrowding should show that they have tried to reduce use of the ED, the weight of this factor should be reduced and consideration given to other factors such as community need for an FMF and limited access to ED and other medical services.

With regard to .04B(1)(iv)(b), AAMC commented that clarification is needed on how "inadequate access" and "access barriers" are defined. AAMC noted than a hospital may have limited ability to affect the policies of local urgent care centers regarding patients who are unable to pay for services. With regard to .04B(1)(b)(vii), AAMC requested clarification on the phrase "low end of the range," a reference to content in the publication referenced in this standard, the American College of Emergency Physician's *Emergency Department Design: A Practical Guide to Planning for the Future.* AAMC also commented on .04B(1)(b)(vii), requesting guidance on how to redirect patients in a manner that is compliant with EMTALA. Finally, AAMC suggested that the "current" community health needs assessment be referenced in .04B(1)(b)(vi) because new three-year community health needs assessments were recently completed.

Staff Analysis and Recommendations

Staff recommends no change in response to LifeBridge Health's recommendation that an FMF be limited to the primary service area of the parent hospital. In rural areas, the requirement for location of an FMF in the primary service area of the parent hospital may be unnecessarily restrictive. Under such a limitation, the FMF currently operated in Queen Anne's County would not have been eligible for a CON, if CON approval had been required for its establishment. In addition, Staff notes that the comparative review standard in the draft Chapter addresses circumstances where one or multiple hospitals with overlapping service areas propose FMFs. With regard to the concerns LifeBridge Health raised regarding physician contracting, Staff added language stating that an applicant should provide information on staffing patterns before and after overcrowding was identified as an issue. This information will be used to assess whether a change in staffing patterns is potentially contributing to overcrowding.

With regard to SOSCA's comments about reducing the weight of certain "need" considerations under this standard, Staff concludes that all standards must be met by applicants. Applicants are not assigned points or partial credit for partly meeting a standard.

With regard to AAMC's comments on .04B(1)(b)(iv) requesting clarification of how inadequate access and access barriers are defined, Staff recommends no changes. The standards in .04B(1)(iv)(b) are deliberately general, and the burden is on the applicant to demonstrate that access barriers exist. However, staff recommends and the draft regulations recommended for adoption clarify the source of the phrase "low end of the range." Staff recommends no change in response to AAMC's comments on .04B(1)(b)(vii). The Commission's role is not to provide advice on compliance with EMTALA, and the standard references reducing the number of patients who inappropriately seek care at emergency departments. Hospitals are expected to take steps to reduce inappropriate use of emergency departments that are consistent with federal and State laws that require evaluation and treatment of individuals who present at a hospital's

emergency department. Lastly, Staff added the word "current" as proposed by AAMC in .04B(1)(b)(vi).

(2) Access

SOSCA commented that the access standards should consider that transport times may be shorter when patients are transported by friends or family members, and these options lower the cost of transport in most situations. SOSCA also commented that the measurement of transport times should be measured from the time of a call for an ambulance, not from when the ambulance arrives at a residence or leaves the residence for a medical facility. In addition, SOSCA commented that the standards should address whether the ambulance service in a community routinely includes EMT staffing and advanced life support because some counties do not have this resource. Lastly, SOSCA recommended that the decision to approve a CON for an FMF should account for the value of improved medical outcomes due to more timely emergency medical treatment.

AAMC requested clarification on whether local emerg ency medical systems will be mandated to share data to enable the applicant to meet the requirements in Paragraph (c).

Staff Analysis and Recommendations

Staff recommends no change in response to SOSCA's comments because transport by ambulance has advantages for some patients, including faster assessment of a patient's medical condition, direct transport to a hospital's emergency department rather than an FMF when appropriate, and sometimes early treatment of a patient's emergency medical condition. Staff also notes that the standard already requires that an applicant address how a proposed project will improve access and that an applicant analyze transport times. Although Staff recognizes the utility of measuring the time from the call for an ambulance and arrival of the ambulance to pick up a patient and the importance of considering the timeliness of emergency medical treatment on patient outcomes, Staff notes that the standards are written generally and do not prevent an applicant from providing the types of information proposed by SOSCA.

Staff recommends no change in response to AAMC's request for clarification because Staff concludes that the standard can be addressed without obtaining data from local emergency medical systems through use of the hospital discharge abstract and outpatient data for Maryland hospitals.

(3) Cost and Effectiveness

Two organizations provided conflicting opinions regarding the required number of alternative approaches that an applicant must evaluate. LifeBridge proposed that applicants be required to consider at least three alternative approaches for achieving the primary objectives of the proposed project, including ED expansion. In contrast, AAMC commented that considering two alternatives would be difficult and overly burdensome. AAMC also requested that the standard include additional details regarding the expectations for coordination of care.

SOSCA commented that the cost of an FMF should consider savings when a hospital is moving and the current ED will be converted to an FMF. SOSCA requested that several other costs also be considered, such as travel costs, the lower costs resulting from improved medical outcomes through timely emergency medical care, and non-financial costs (stress level) for friends, family, and others.

In response to the draft posted in December 2015, UMMS suggested that Paragraph (b) be modified to refer specifically to the emergency services for the proposed project. UMMS subsequently commented, in response to the draft posted in June 2016, that the time period for revenue and expense projections for a proposed FMF in Section .04B(3)(a)(i) should include a specific time period, rather than referring to a "time period appropriate for evaluating cost effectiveness." UMMS explained that specifying the time period would allow the Commission to more easily compare applications. UMMS proposed that a period of three years or longer be considered.

Staff Analysis and Recommendations

Staff recommends no change in response to AAMC's comments. The requirement for an evaluation of alternative approaches to meeting the primary objectives of a proposed project is necessary to evaluate the cost effectiveness of proposed projects. The requirement is consistent with the approach taken in other recently updated SHP chapters.

With regard to LifeBridge's proposal to require an evaluation of three alternatives, Staff also recommends no change because if an applicant initially chooses not to evaluate an obvious viable alternative, Staff may request that an applicant evaluate this alternative before deeming an application complete or may recommend that the Commission find that an applicant has not met the standard.

Staff recommends no change in response to SOSCA's comments because the regulations do not exclude consideration of the specific costs referenced by SOSCA, and the specific costs mentioned may not be applicable to all proposed projects.

Staff also recommends no changes in response to AAMC's request for additional details regarding the expectations for coordination of care. Staff concluded that Paragraph (e) appropriately requests that an applicant describe its care coordination initiatives and its evaluation of the success of these initiatives at the hospital's emergency department, as well as its plans for the proposed FMF. There is neither an ideal care coordination model nor pre-determined outcomes against which an applicant will be judged.

Staff recommends no change in response to UMMS's suggestion that Paragraph (b) refer specifically to the emergency services because Staff determined that this proposed change was no longer needed, based on the addition of language in a separate section that addresses requests for exemptions from CON review, when a hospital is converting to an FMF.

Staff modified the language in Section .04B(3)(a)(i), as requested by UMMS, to specify that an applicant should provide projections of revenue and expenses for five years for a

proposed FMF. Staff agrees with UMMS that specifying the time period will facilitate a comparison of FMF projects.

(4) Efficiency

UMMS suggested that Paragraph (a) be modified to refer specifically to the emergency services for the proposed project, in response to the draft posted in December 2015. UMMS also commented on this standard in response to the draft posted in June 2016. UMMS requested deletion of the language requiring that an applicant present its analysis of how the establishment, relocation, or expansion of the FMF will affect the efficiency of emergency services delivery be presented to all of the hospitals in the proposed or existing service area for the opportunity to comment. UMMS expressed concern that it creates a channel for a third party to assert procedural rights in a CON proceeding, when there is already a mechanism for a party to participate in the CON proceeding when a party meets the statutory and regulatory definition of "interested party." Dimension Healthcare System also expressed support for the comments of UMMS on the draft posted in June 2016. AAMC commented that additional details regarding the analysis of efficiency required for presentation to the emergency medical system should be included.

Staff Analysis and Recommendations

Staff recommends no changes in response to the comments from UMMS on the draft posted in December 2015 because the standard in Paragraph (a) is intended to refer to emergency service delivery in the service area of the proposed project rather than only emergency services provided at the proposed FMF. In response to UMMS' comments on the draft posted in June 2016, Staff deleted language, as requested by UMMS. Staff concluded that there is sufficient opportunity for public comment and participation without the deleted language.

Staff recommends no changes in response to AAMC's request for additional details regarding the required analysis of efficiency that must be presented to the emergency medical system. Staff concludes that it is sufficient to refer to emergency transport, which should be understood to mean travel times for emergency vehicles, and hospital ED and FMF operations, which may include many different measures of efficiency. Staff concludes that providing some flexibility is appropriate, and if there are deficiencies in the analysis presented, then an applicant will receive constructive feedback from the emergency medical services system and Staff. An applicant will then have the opportunity to make any necessary corrections.

(6) Financial Feasibility and Viability

In response to the draft posted in December 2015, UMMS suggested that Subparagraph (b)(i) be modified to refer specifically to the emergency services provided at the proposed FMF, based on its assumption that services provided by an FMF will encompass more than just emergency services in some cases.

Adventist HealthCare suggested that the language in .04B(6)(b) be consistent with the language in .04B(7), referring to an "undue" adverse impact rather than "severe." In response to

the draft posted in June 2016, UMMS recommended that rather than referring to "an undue negative effect on the financial viability of the parent hospital," the standard should refer to not jeopardizing the long-term viability of the parent hospital. UMMS stated that the standard focuses on the negative impact that an FMF may have on the parent hospital rather than the financial performance of the two facilities as a combined unit. Dimensions Healthcare also expressed general support for UMMS comments on the draft posted in June 2016. The specific changes recommended by UMMS, with strikethroughs for proposed deletions and double underlining for new language: "The proposed establishment, expansion, or relocation of an FMF shall be financially feasible and shall not ~~have an undue negative effect on the financial~~ jeopardize the long-term viability of the parent hospital."

Staff Analysis and Recommendations

Staff made the change proposed by Adventist HealthCare because the proposed change is consistent with the terminology for the impact standard. Staff recommends no changes in response to the comments from UMMS on Subparagraph (b)(i) of the draft posted in December 2015 because the financial feasibility projections should be based on all services provided by an FMF. As indicated in the regulations, these services are expected to be emergency services analogous to those provided by the applicant hospital's ED, when a CON is required to establish an FMF. Staff also recommends no changes in response to comments from UMMS on Paragraph .04B(6)(b) of the draft Chapter posted in June 2016 because the proposed change would require an exceptionally negative effect, which is not consistent with the intent of Staff or the approach taken with respect to other CON regulated services. Staff also notes that an FMF is administratively part of the parent hospital, and the proposed standard focuses on the combined financial performance of the two facilities.

(7) Impact

Adventist HealthCare expressed concern about FMFs being used as a business strategy to shift market share from another hospital and suggested that the term "undue negative effect" be further clarified.

LifeBridge suggested that this section include specific reference to the impact of the proposed FMF on population health programs of other hospitals and the parent hospital for the proposed FMF. AAMC commented that the impact on global budgets of other hospitals should be explicitly considered. AAMC also commented that the requirement that a proposed FMF not have a "severe impact" on another hospital is unclear and is not consistent with the approach taken for other services regulated through CON. SOSCA commented that under Paragraph (c) of the impact standard, an applicant should be required to address the cost and savings to the community as a result of greater access to emergency medical services. Lastly, UMMS noted that there is a typographical error in Standard .04B(7)(b).

Staff Analysis and Recommendations

Staff recommends no changes to further define "undue negative effect," as requested by Adventist HealthCare, because there is too little experience with the development of FMFs to

inform a more specific definition of "undue negative effect." Staff notes that similar wording is used in other SHP chapters, and the benefits of a proposed FMF project may appropriately affect the Commission's perception of "undue negative effect." Staff agrees with using consistent terminology in this impact standard and concluded that the phrase "severe impact" in Paragraph (b) should be replaced with "undue adverse impact."

Staff recommends no change to specifically reference the impact of a proposed FMF on the population health programs of other hospitals. Staff notes that the general requirement to address the impact of a proposed FMF on other hospitals covers the concern raised by LifeBridge. If an applicant has not sufficiently addressed the impact of a proposed FMF on other hospitals in the CON application, Staff may not deem an application to be complete. Staff also recommends that an applicant not be specifically required to address the impact of the proposed FMF on the population health program of the parent hospital as part of this standard. The intent of the impact standard is to focus on hospitals other than the applicant (parent) hospital.

With regard to SOSCA's comments on Paragraph (c), Staff recommends no changes because the standard already requires an applicant to address how costs will change as a result of the proposed project, allowing an applicant to consider both increases and reductions in costs.

Staff agrees with AAMC that the impact of a proposed FMF on the global budgets of other hospitals should be considered when such information is applicable and available. HSCRC maintains authority over the global budgets of Maryland hospitals. Therefore, Staff added language stating that any analyses by HSCRC regarding the impact of a proposed FMF on other hospitals global budgets will be considered by the Commission.

Staff corrected the typographical error noted by UMMS.

(8) Quality Improvement

Both UMMS and MIEMSS suggested a change in the first sentence of the quality improvement standard. UMMS proposed referring to "medical services" rather than specifically "emergency medical services." MIEMSS proposed deleting the word "medical" because "emergency medical services" typically means care provided prior to a patient's arrival at a hospital. UMMS also proposed changing the second sentence under (8)(a) to refer to "emergency services" specifically and noted a minor correction in this section. AAMC commented that patients from both the FMF and the hospital ED may be waiting for inpatient beds and requested clarification on who takes priority for bed placement.

Staff Analysis and Recommendations

Staff recommends no change in response to UMMS' comments because the intent is to focus specifically on emergency services. Staff also concludes that the other proposed change by UMMS is restrictive and not consistent with one of the requested quality metrics listed, the percentage of patients who left the ED or FMF prior to evaluation by a physician. Staff made the minor correction noted by UMMS in this section, deleting the word "the" in one instance.

Staff made the changes proposed by MIEMSS for clarity, consistent with Staff's decision to make other similar changes requested by MIEMSS throughout the draft Chapter.

Staff recommends no changes in response to AAMC's comments because it is not appropriate or necessary for this Chapter to address the manner in which hospitals manage ED or FMF throughput to appropriately prioritize the queuing of patients for admission to the hospital.

(9) Preference in Comparative Reviews

Adventist HealthCare stated that the regulations cite criteria for choosing between competing applications in a comparative review but do not state that the Commission has the option to choose *neither* application. They commented that this should be clarified. AAMC requested more detail on how an FMF operation will be integrated with primary care delivery. SOSCA commented that language should be included in this standard that addresses benefits to the local community and demonstrated community support for an FMF.

Staff Analysis and Recommendations

Staff recommends no change in response to Adventist HealthCare's suggestion that this standard explicitly state that the Commission may choose neither application. The basis for choosing neither application would likely be a failure of either applicant to meet one or more applicable standards. The preference standards apply only when both applicants meet all of the standards in the Chapter.

Staff also recommends no change in response to AAMC's comment. This standard is not intended to prescribe a specific model for integrating operation of an FMF with primary care. Instead, it is intended to provide applicants with flexibility in demonstrating how the goal of linking patients using a hospital ED or FMF to regular sources of primary care will be achieved.

Lastly, Staff recommends no change in response to SOSCA's comment. It would be challenging for the Commission to measure and compare the level of community support for an FMF, and Staff concludes that preference should be awarded based on benefits to the health care system as a whole, to a region of the State, or a historically disadvantaged population group, rather than the local community, as reflected in the current draft standards for preference in comparative reviews.

C. Exemption from Certificate of Need Review to Convert a General Hospital to a Freestanding Medical Facility

UMMS proposed that draft COMAR 10.24.19.04C(7) include language that requires an applicant to demonstrate the need for operating room capacity consistent with COMAR 10.24.11.06, which is a reference to part of the State Health Plan Chapter for surgical services. UMMS also proposed modifying the requirements in COMAR 10.24.19.04C(7)(f)(iii) to include reference to other outpatient services at the applicant hospital's ED rather than the recent experience of similar FMFs. UMMS also proposed deleting the reference to hospital

EDs in draft COMAR 10.24.19.04C(7)(h) and proposed instead referencing services provided at hospitals generally. Dimensions Healthcare System also expressed support for the comments of UMMS.

UMMS commented that applicants should not be required to obtain information on other FMFs, as stated in .04C(7)(f). UMMS stated that the information may be difficult to obtain, especially from FMFs owned or operated by competitors. UMMS proposed that this requirement be deleted and proposed adding a reference to outpatient services at the applicant hospital's ED. Dimensions Healthcare System also expressed support for these comments.

UMMS commented that, in draft COMAR 10.24.19.04C(2)(c), the language should be revised to make it clear that only one public hearing is required for the conversion of a general hospital to an FMF. UMMS explained that the draft Chapter could be interpreted to mean that a hospital must hold a public hearing prior to filing its notice of intent to seek an exemption for conversion to an FMF and then hold another public hearing once the exemption has been granted because conversion would constitute a closure or partial closure of a hospital. Dimensions Healthcare System also expressed support for the comments of UMMS.

Staff Analysis and Recommendations

Staff added language in a separate subsection, COMAR 10.24.19.04C(9) to specify the standards an applicant is required to meet, if establishment of an ambulatory surgical facility is proposed in conjunction with development of an FMF. Staff concludes that this change will effectively address the proposed changes proposed by UMMS to draft COMAR 10.24.19.04C(7)(f)(iii)

Staff recommends no changes to address UMMS's comments regarding draft COMAR 10.24.19.04C(7)(h). Staff disagrees that expecting applicants to obtain comparative information from FMFs is unreasonable. A similar requirement exists for ambulatory surgical capacity, and previous CON applications are often used as one source of information. Staff expects that CON applications for FMFs or CON exemption requests will serve as one source of this information. Applicants may also solicit information from similar facilities located outside of Maryland who would not be regarded as competitors.

Staff recommends no changes to address UMMS's concern that a second public hearing will be required after an exemption to establish an FMF has been granted. However, Staff added a separate subsection .04C(11) that provides that a general hospital that decides it will close because the Commission denied an applicant's request for an exemption from CON to establish an FMF or as a result of a determination made by the State Emergency Medical Services Board must provide notice of closure and hold a public informational hearing as required by Health-General 19-120.

Definitions

AAMC commented that the definition of "freestanding medical facility" should be more detailed with regard to the services that must be provided 24 hours per day and seven days a

week. AAMC noted that the existing FMFs may transfer patients to a hospital's emergency department for care and diagnostic tests that should be available at an FMF, causing additional expense and inconvenience for the patient and hospital receiving the transferred patient.

MIEMSS proposed that the definition of "emergency medical condition" be modified to be consistent with the EMTALA definition. In addition, MIEMSS proposed that the definition of "freestanding medical facility" be clarified.

Staff Analysis and Recommendations

With regard to AAMC's request to include additional detailed information on the required services to be provided at an FMF, Staff recommends no change. The required services are already included in the licensure regulations for freestanding medical facilities. Staff changed the definitions for "emergency medical condition" and "freestanding medical facility" to address the concerns identified by MIEMSS.

Other Comments

AAMC commented that a hospital may believe that an FMF is needed, but the cost may be prohibitive due to competition from urgent care and the retail care market that results in the FMF caring for patients with higher acuity and indigent patients. In addition, AAMC expressed concern that urgent care centers potentially have the ability to undercut the policy objectives in the draft Chapter, in particular, access to appropriate care.

David B. Paris, Esquire, proposed that licensing of combined freestanding emergency and urgent care centers be required. He stated that these integrated facilities discourage the use of hospital EDs for sporadic crisis visits by promoting the establishment of long-term relationships with primary care providers and specialists.

Mr. Paris also proposed that the Chapter require the evaluation of any relocated general hospital and any FMF that is to be left behind, during a comprehensive CON review process. He also proposed that a "truncated review process" should be available for an FMF in Takoma Park. Similarly, the City of Takoma Park also requested an "expedited review process" for a hospital that is relocating within its existing service area that is seeking to establish an FMF on its previous campus and that meets several other criteria that would apply to Takoma Park. The City of Takoma Park also explained the rationale for an FMF in Takoma Park based on consistency with the policies in the draft Chapter.

Mr. Paris commented that the State of Maryland should mandate impact studies for any proposed hospital closing or downsizing to be integrated into the CON review process. Mr. Paris recommended legislation be passed to provide for objective medical impact studies, rather than proposing specific changes to the draft Chapter.

Staff Analysis and Recommendations

Staff recommends no additional changes in response to the issues raised by AAMC. The Commission does not have the authority to regulate urgent care centers, which are not operated as licensed health care facilities in Maryland. Staff concludes that the draft regulations include appropriate language that emphasizes avoiding inappropriate use of emergency departments and evaluating alternative ways to meet the needs of the population to be served by a proposed FMF. Staff recommends no additional changes in response to the issues raised by AAMC.

Staff recommends no changes in response to the suggestion of Mr. Paris that the State require licensing of combined freestanding emergency and urgent care centers. Staff concludes that by requiring an applicant for a CON to establish an FMF to describe the steps that it has taken or will initiate to promote the coordination of care with providers of primary care, as well as, its evaluation of the success of these processes, the draft Chapter is promoting the goals that Mr. Paris identified in his comments. The mechanism that Mr. Paris proposes for achieving these goals is only one of several possible mechanisms, and Staff concludes that it is appropriate to give an applicant flexibility.

Staff recommends no changes in response to Mr. Paris's request that the CON review process for a relocated general hospital also include an evaluation of an FMF, if an FMF is proposed for the old site of the general hospital. Staff concludes that the draft Chapter permits consideration of an FMF as part of the CON review for a relocated general hospital. All of the standards for CON review of an FMF would apply.

With regard to providing an expedited or truncated review process for an FMF in Takoma Park, as requested by Mr. Paris and the City of Takoma Park, Staff also recommends no changes. The acute care general hospital in Takoma Park, Washington Adventist Hospital, received approval for relocation of the hospital from Takoma Park to Silver Spring, and it did not propose establishment of an FMF on the Takoma Park campus. During the CON review for the proposed relocation of Washington Adventist Hospital, the Commissioners heard arguments that urged the MHCC to require Adventist HealthCare to establish an FMF at the Takoma Park campus as a condition of CON approval of the hospital's relocation. Commissioner/Reviewer Frances Phillips recommended against such a condition, stating that she did not believe that it was prudent or appropriate to require Adventist HealthCare to commit to the more expensive FMF model of urgent and emergent care delivery. Commissioner Phillips noted her recommendation of a CON condition requiring Adventist HealthCare to open a 24/7 urgent care center on its Takoma Park campus when it closed its general hospital operations and providing that the urgent care center could not eliminated or its hours changed without Commission approval. Staff concludes that the proposed process for handling a CON request to establish an FMF, including when a hospital is relocating and seeks to establish an FMF on the current hospital campus, is unlikely to pose an excess burden for applicants.

Staff recommends no changes in response to Mr. Paris's proposal that objective impact studies be integrated into the CON process. The impact of proposed CON projects is evaluated based on information provided by an applicant, interested parties, and Staff's own research as

needed. Staff notes that a hospital that is downsizing and seeking to replace the hospital with an FMF is required to hold a public informational hearing that addresses the health care needs of residents of the hospital's service area and the timeline for conversion. The hearing also provides an opportunity for public input on the hospital's plan. Staff concludes that the proposed process and standards are adequate for evaluating the impact of a proposed CON project.